

Applicant respectfully requests that pages 1-4 and 6-38 of Exhibit C of the above-identified application be expunged.

MPEP 724.05 I.(B) provides that a proper Petition to Expunge must clearly state that the information to be expunged is trade secret material, proprietary material and/or subject to a protective order, and that the information has not been otherwise made public.

The information set forth on pages 1-4 and 6-38 of Exhibit C is trade secret material and/or proprietary material. The information has not otherwise been made public by the Applicant. However as recognized by the PTO, the information was forwarded by the PTO to the U.S. Food and Drug Administration (FDA) as part of the complete application for patent term extension. The Applicant's undersigned representative spoke by telephone with Ms. Jennifer Butler, Director of Dockets Management of the FDA on December 14, 2006. Ms. Butler informed the undersigned that the application has not yet been published on the internet but the application has been available to the public in the FDA public search room. The undersigned informed Ms. Butler that Exhibit C was mistakenly included in the application for patent term extension and contains trade secret and/or proprietary material of the Applicant. Ms. Butler confirmed that each page of Exhibit C is clearly marked at the top of the page "Confidential Document Takeda Property".

The undersigned requested that Exhibit C be removed from the public search room copy of the application. Ms. Butler agreed to remove Exhibit C from the public search room copy. Ms. Butler also stated that when the application is published by the FDA on the internet, the application will not contain Exhibit C.

Subsequently the undersigned spoke with Ms. Butler on December 15, 2006. Ms. Butler confirmed that Exhibit C was removed from the public search room copy on December 14, 2006. There is no way to determine whether any member of the public viewed the application. Nevertheless as of the date of December 15, 2006, the only publicly available copy of Exhibit C is the copy published by the PTO.

MPEP 724.05 I.(C) provides that the Petitioner commit to retain such information for the period of any patent with regard to which such information is submitted.

Petitioner/Applicant hereby expressly commits to retain the information for the period of any patent with regard to which the information was submitted, namely U.S. Patent No. 6,034,239.

MPEP 724.05 I.(D) provides that the petition include a statement that the petition to expunge is submitted by or on behalf of the party in interest who originally submitted the information.

The party in interest who originally submitted the information is Takeda Pharmaceutical Company Limited (Takeda). The Petition to Expunge was filed by an authorized representative of Takeda. The undersigned is an authorized representative of Takeda, as shown by the Associate Power of Attorney attached hereto. Thus the Petition to Expunge and the instant Request for Reconsideration are submitted by or on behalf of the party in interest who originally submitted the information.

MPEP 724.05 I.(E) provides that the fee set forth in 37 C.F.R. 1.17(g) be required. This fee was charged in connection with the filing of the Petition to Expunge.

MPEP 724.05 II.(A) provides that a petition to expunge may be filed provided that the PTO can effect such return prior to the issuance of any patent on the application in issue.

The instant application will not issue into a patent. In due course the PTO is expected to issue a Certificate of Patent Term Extension. However this Request for Reconsideration is submitted prior to issuance of the Certificate of Patent Term Extension and on the date the FDA's determination of regulatory review period becomes final. Hence it is respectfully submitted that this Request is submitted in good time before issuance of the Certificate of Patent Term Extension.

MPEP 724.05 II.(B) provides that the Petition include a statement that the information was unintentionally submitted and the failure to obtain its return would cause irreparable harm to the party who submitted the information or the party in interest on whose behalf the information was submitted.

The information contained in pages 1-4 and 6-38 of Exhibit C was unintentionally submitted by the party in interest, Takeda. The failure to obtain its return would cause irreparable harm to Takeda. Takeda has invested more than \$100 million in the development of ROZEREM for the treatment of insomnia. Approximately 60 million people in the United States suffer from insomnia. Despite numerous sleep aid products on the market, such products suffer from side effects, weak effect, etc. and don't help all patients with insomnia. ROZEREM is a major improvement in insomnia medicines as the first and only prescription sleep medication that has

shown no evidence of abuse and dependence. As a result, ROZEREM has not been designated as a controlled substance by the U.S. Drug Enforcement Administration (DEA). Moreover ROZEREM is the first prescription insomnia medication with a new therapeutic mechanism of action in 35 years.

The information contained in Exhibit C is trade secret and proprietary information to Takeda. Exhibit C was accidentally included in the Takeda PTE application. Exhibit C provides detailed information on ROZEREM. Takeda has spent over than 10 years inventing and developing ROZEREM. Release of this information to the public will cause irreparable harm to Takeda in the way that public knowledge of Exhibit C would give Takeda's competitors a very strong advantage in developing and marketing generic ROZEREM in the future. Thereby, Takeda's competitors with the proprietary knowledge of Exhibit C could sell ROZEREM for far less than Takeda itself, since Takeda must sell ROZEREM at a price that recoups at least some of its huge investment.

The foregoing explanation is believed to be sufficient to show why Takeda will be irreparably harmed if Exhibit C is not returned to Takeda.

MPEP 724.05 II.(C) provides that the information has not otherwise been made public.

In reply, please see the Applicant's response to MPEP 724.05 I.(B) above.

MPEP 724.05 II.(D) provides that the Petitioner commit to retain such information for the period of any patent with regard to which such information is submitted.

In reply, please see the Applicant's response to MPEP 724.05 I.(C) above.

MPEP 724.05 II.(E) provides that it is established to the satisfaction of the Director that the information to be returned is not material information under 37 C.F.R. 1.56.

The information contained in pages 1-4 and 6-38 of Exhibit C is not material information under 37 C.F.R. 1.56. The information is not prior art. The information is trade secret and/or proprietary analytical information about the compound approved by the FDA and claimed in U.S. Patent No. 6,034,239.

Lastly, MPEP 724.05 II.(F) provides that the fee set forth in 37 C.F.R. 1.17(g) be required. As noted above in the response to MPEP 724.05 I.(E), this fee was charged in connection with the filing of the Petition to Expunge.

It is believed that the foregoing will place the Applicant's Petition to Expunge in compliance with all applicable PTO rules and guidelines.

In summary, it is respectfully requested that the PTO grant this Petition to Expunge pages 1-4 and 6-38 of Exhibit C of this application. In enacting 37 C.F.R. 1.59(b), the PTO has recognized that on occasion, mistakes occur in the submission of information in an application. The PTO has provided a mechanism to allow for correction of these mistakes in appropriate circumstances by a Petition to Expunge. It is respectfully submitted that this instance is one such appropriate circumstance. The information was unintentionally submitted and will cause irreparable harm to Takeda if it remains open to the public. There is no knowledge or information or belief that the information has actually been viewed by any member of the public. Expunging the information will cause no harm to the public. It is respectfully suggested that granting of this Petition is appropriate in view of the total circumstances.

Favorable reconsideration is respectfully requested. Please contact the undersigned if you have any questions.

Respectfully submitted,

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